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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,499	12/05/2003	Norberto A. Guzman	57430-8	9723

7590 08/09/2005

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EXAMINER

JUNG, UNSU

ART UNIT PAPER NUMBER

1641

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/728,499

Applicant(s)

GUZMAN, NORBERTO A.

Examiner

Unsu Jung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-321 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-321 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-39, drawn to an electrophoresis apparatus, classified in class 422, subclass 50, for example.
 - II. Claims 40-77, drawn to an electrophoresis apparatus having a transport capillary and at least one separation capillary, classified in class 435, subclass 287.2, for example.
 - III. Claims 78 and 79, drawn to a system for replacing a plurality of affinity ligands adapted to attract at least one analyte of interest from a sample solution, classified in class 435, subclass 283.1, for example.
 - IV. Claims 80-86, drawn to an electrophoresis apparatus, classified in class 435, subclass 285.2.
 - V. Claims 87-90, drawn to an electrophoresis apparatus, classified in class 422, subclass 68.1, for example.
 - VI. Claims 91-101, drawn to a method of forming a substantially consistent Fab fragment, classified in class 436, subclass 512, for example.
 - VII. Claims 102-140, drawn to an electrophoresis apparatus, classified in class 422, subclass 82.05, for example.
 - VIII. Claims 141-178, drawn to an electrophoresis apparatus having a transport channel adapted to provide a sample solution to be analyzed and at least

one separation channel, classified in class 435, subclass 287.1, for example.

- IX. Claims 179 and 180, drawn to a system for replacing a plurality of affinity ligands adapted to attract at least one analyte of interest from a sample solution, classified in class 435, subclass 283.1, for example.
- X. Claims 181-187, drawn to an electrophoresis apparatus, classified in class 422, subclass 63, for example.
- XI. Claims 188-201, drawn to an electrophoresis apparatus, classified in class 422, subclass 81, for example.
- XII. Claims 202-206, drawn to an electrophoresis apparatus, classified in class 422, subclass 67, for example.
- XIII. Claims 207-230, drawn to a method of identifying a plurality of analytes of interest from a sample solution, classified in class 436, subclass 518, for example.
- XIV. Claims 231-268, drawn to a method of identifying a plurality of analytes of interest from a sample solution, classified in class 435, subclass 4, for example.
- XV. Claims 269-306, drawn to method of identifying a plurality of analytes of interest from a sample solution, classified in class 436, subclass 523, for example.
- XVI. Claims 307-311, drawn to a system for detecting biomarkers associated with a disease, classified in class 422, subclass 55, for example.

XVII. Claims 312-321, drawn to a method for detecting a disease from a specimen provided by an individual, classified in class 436, subclass 519, for example.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I-V, VII-XII, and XVI are independent and patentably distinct.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the apparatus of Group I includes a plurality of separation capillaries coupled to a transport capillary capable of directing flow and a plurality of valves located on the transport and the plurality of separation capillaries, where the valves on the transport capillary control the flow of the sample solution through the transport capillary and the valves on the plurality of separation capillaries control the flow of fluid through each of the plurality of separation capillaries, which are not included in the apparatuses and systems of Groups II-V, VII-XII, and XVI. The apparatus of Group II includes at least one analyte concentrator at the intersection between a transport capillary and at least one separation capillary and a plurality of valves on the transport and separation capillaries to surround analyte concentrator to control flow of the sample and buffer solutions to the analyte concentrator, which are not required by the apparatuses and systems of Groups I, III-V, VII-XII, and XVI. The system of Group III includes a first capillary system and an electrophoresis apparatus having a platform adapted to releasably couple to the

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capillary system, which are not required by the apparatuses and systems of Groups I, II, IV, V, VII-XII, and XVI. The apparatus of Group IV includes a plurality of separation capillaries capable of directing flow of fluid coupled to a transport capillary to form a plurality of analyte concentrators, where the transport capillary is staggered along at least one of the plurality of separation capillaries so that the analyte concentrator formed along the at least one of the separation capillaries is elongated. These elements are not required by the apparatuses and systems of Groups I-III, V, VII-XII, and XVI. The apparatus of Group V includes a plurality of separation capillaries, each separation capillaries having an inlet and an outlet, coupled to a transport capillary to form a plurality of analyte concentrators and an auxiliary capillary coupled to at least one of the separation capillaries between the analyte concentrator and the outlet, which are not required by the apparatuses and systems of Groups I-IV, VII-XII, and XVI. The apparatus of Group VII includes a plurality of separation channels coupled to a transport channel forming a plurality of analyte concentrators and a plurality of valves located on the transport channel and on the plurality of separation channels, where the valves on the transport channel control the flow of a sample solution through the transport channel and the valves on the plurality of the separation channels control the flow of fluid through each of the plurality of the separation channels, which are not required by the apparatuses and systems of Groups I-IV, VIII-XII, and XVI. The apparatus of Group VIII includes at least one analyte concentrator at the intersection between a transport channel and at least one separation channel and a plurality of valves on the transport and separation channels to surround the analyte concentrator to control the flow of a

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sample and buffer solutions to the analyte concentrator, which are not required by the apparatuses and systems of Groups I-IV, VII, IX-XII, and XVI. The system of Group IX includes a first channel system and an electrophoresis apparatus having a platform adapted to releasably couple to the channel system, which are not required by the apparatuses and systems of Groups I-IV, VII, VIII, X-XII, and XVI. The apparatus of Group X includes a plurality of separation channels capable of directing fluid flow coupled to a transport channel to form a plurality of analyte concentrators, where the transport channel is staggered along at least one of the plurality of separation channels so that the analyte concentrator formed along at least one of the separation channels is elongated, which are not required by the apparatuses and systems of Groups I-IV, VII-IX, XI, XII, and XVI. The apparatus of Group XI includes a plurality of separation channels, each separation channel having an inlet and an outlet capable of directing flow of first fluid from the inlet to the outlet, coupled to a transport channel to form a plurality of analyte concentrators and an auxiliary channel coupled to at least one of the separation channels between the analyte concentrator and the outlet, which are not required by the apparatuses and systems of Groups I-IV, VII-X, XII, and XVI. The apparatus of Group XII includes a means for isolating a plurality of analytes of interest from a sample solution into a corresponding plurality of areas and means for localizing the plurality of areas to improve the means for isolating the plurality of analytes of interest, which are not required by the apparatuses and systems of Groups I-IV, VII-XI, and XVI. The system of Group XVI includes a CPU, which is not required by the

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apparatuses and systems of Groups I-IV and VII-XII. Therefore, the apparatuses and systems of Groups I-V, VII-XII, and XVI have different modes of operation.

4. Inventions VI, XIII, XIV, XV, XVII and I-V, VII-XII, XVI are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatuses and systems of Groups I-V, VII-XII, XVI can be used to practice another and materially different process. For example, the apparatuses and systems of Groups I-V, VII-XII, XVI can be used with an immunosubtracting capillary electrophoresis assay using a modified antibody.

5. Inventions VI, XIII, XIV, XV, and XVII independent and patentably distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of Group VI includes a step of freeing a glycosylated IgG of sugar by at least one glycosidase to form a deglycosylated IgG, which is not required by the methods of Groups XIII, XIV, XV, and XVII. The method of Group XIII includes a step of providing a plurality of areas where each area is capable of having affinity for at least one analyte of interest from a sample solution, which is not required by the methods of Groups VI, XIV, XV, and XVII.

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The method of XIV includes a step of intersecting a plurality of separation capillaries to a transport capillary, which is not required by the methods of Groups VI, XIII, XV, and XVII. The method of Group XV includes a step of intersecting a plurality of separation channels to a transport channel, which is not required by the methods of VI, XIII, XIV, and XVII. The method of Group XVII includes a step of automatically isolating a plurality of biomarkers from a specimen, which is not required by the methods of Groups VI, XIII, XIV, and XV.

6. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art because of their recognized divergent subject matter, and searches for one group are not required by the others, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Unsu Jung whose telephone number is 571-272-8506. The examiner can normally be reached on M-F: 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Unsu Jung, Ph.D.
Patent Examiner
Art Unit 1641



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08/08/05